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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,009	03/11/2004	Lee R. Dreyer	025803-00003	3896

4372 7590 12/21/2005

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EXAMINER	
FLOOD, MICHELE C	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/797,009	DREYER, LEE R.	
	Examiner	Art Unit	
	Michele Flood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) *2-9,15-18 and 21-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,10-14,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on September 21, 2005.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

This application contains claims 21-49 drawn to an invention nonelected with traverse on March 29, 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The originally elected species was not found; therefore the requirement for species election has been withdrawn. The Claims were examined on the merits taking each of the species of the Markush Group in Claims 1 into consideration.

Claims 1-20 are under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, as amended, and Claims 10-13 is/remain rejected under 35 U.S.C. 102(b) or at least 102 (a) as being anticipated by King Bio Natural Medicines, as evidenced by Dr. Frank J. King (V) and Internet Archive Wayback Machine (W). Full consideration was given to each and every argument presented by Applicant. However, the rejection remains for the reasons set forth in the previous Office action and for the reasons set forth below.

Applicant claims a formulation for topical use comprising herbal active ingredients and a base suitable for topical penetration of the skin, wherein the herbal active ingredients comprise:

(a) tinctures and/or homeopathic preparations of 8 or all of Bellis perennis, Calendula officinalis, Hamamelis virginiana, Arnica Montana, Hypericum perforatum, Aconitum napellus, Ledum palustre, Bryonia alba and Ruta graveolens; or

(b) tincture and/or homeopathic preparations of at least 5, 6 or 7 of Bellis perennis, Calendula officinalis, Hamamelis virginiana, Arnica Montana, Hypericum perforatum, Aconitum napellus, Ledum palustre, and Ruta graveolens; or

(c) tinctures and/or homeopathic preparations of at least 5, 6 or 7 of Bellis perennis, Calendula officinalis, Hamamelis virginiana, Arnica Montana, Hypericum perforatum, Aconitum napellus, Ledum palustre, Bryonia alba and Ruta graveolens, with the proviso that the formulation does not contain tincture(s) and/or homeopathic preparation(s) of Echinacea augustifolia and Symphytum officinale.

Applicant further claims the formulation of claim 1, the herbal active ingredients comprising tinctures and/or homeopathic preparations of at least 5, 6 or 7 of Bellis perennis, Calendula officinalis, Hamamelis virginiana, Arnica Montana, Hypericum perforatum, Aconitum napellus, Ledum palustre, Bryonia alba and Ruta graveolens, with the proviso that the formulation does not contain tincture(s) and/or homeopathic preparation(s) of Echinacea augustifolia and Symphytum officinale.

Firstly, Applicant argues that the examiner has failed to establish conclusively that the same cited version of "911 Stress Control 2 oz Liquid" appeared on the world wide web as early as February 23, 2002 because the archived web page was devoid of any listing of ingredients. Applicant submits that an archived web page of "911 Stress Control 2 oz Liquid" disclosing a listing of the ingredients of the referenced composition appeared on the world wide web only as early as June 7, 2002. Thus, Applicant concludes that the reference cannot constitute a rejection against Claim 1 and Claims 10 to 13 under 35 USC § 102 because of the priority date of the present application (March 14, 2003), even in view of the "proffered testimony from the examiner's telephonic interview of Dr. King", which Applicant argues is unsubstantiated by the aforementioned facts. Secondly, Applicant argues that the formulation of the instantly claimed invention "is an external topical analgesic pain relief product, while the referenced composition is an "oral internal mental and emotional stress formula only"; and, that Dr. King's inclusion of 20 drugs in the referenced composition cannot anticipate Applicant's instantly claimed composition. However, Applicant's arguments are neither persuasive nor commensurate in scope to the limitations of the instantly

claimed invention because while Applicant suggests that the composition taught by Dr. King is an allopathic drug versus a homeopathic drug and that the ingredients comprising the referenced composition may provide a therapeutically insufficient, nonexistent or placebo effect, the Office notes that nowhere in the limitations of the claims as drafted does Applicant direct the subject matter of the invention to an external topical analgesic pain relief product. Thus, the prior art reference is still deemed to anticipate the claimed subject matter because King Bio Natural Medicines teaches a formulation, "911 Stress Control 2 oz Liquid", comprising homeopathic preparation of *Bryonia alba* and homeopathic preparations of *Bellis perennis, Calendula officinalis, Arnica Montana, Hypericum perforatum* and *Aconitum napellus*, wherein each ingredient is in equal volumes of 10X, 30X, and 100X potencies in a pure water base. As evidenced by the information provided by Internet Archive Wayback Machine, the provided webpage teaching the aforementioned product appeared on the world wide web as early as February 23, 2002; and as further substantiated by a telephonic interview, wherein on June 9, 2005, Dr. Frank J. King (Founder and President of King Bio Natural Medicine, Inc.) stated that the aforementioned product was in public use and for sale in March 1990, absent evidence to the contrary. Please note that a rejection under 35 USC § 102 is proper unless "(b) the invention was patented or described in a printed publication in this or a foreign country **or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States**." Given that the cited reference teaches a composition comprising the same ingredients and the same amounts of the same ingredients, and given that the

cited reference teaches the referenced composition as a homeopathic composition, and given that the telephonic interview of the Office with Dr. King provides evidence that the cited reference of King Bio Natural Medicines formulation of "911 Stress Control 2 oz Liquid" was in public use or on sale in this country more than one year prior to the date of the present application for patent in the United States, absent evidence to the contrary, the cited prior art is still deemed to anticipate the instantly claimed subject matter. Furthermore, given that there is no ingredients contained therein the prior art reference to preclude use thereof for topical use, the referenced composition is considered as a formulation for topical use comprising the claim-designated herbal active ingredients and the claim-designated amounts thereof, and a base suitable for topical penetration of the skin, namely water, given that Applicant readily admits that water is within the meaning of the term "a base suitable for topical penetration of the skin" at [0049] of US 2004/01280101 A1 Patent Application Publication.

The reference anticipates the claimed subject matter.

Claim 1, as amended, and Claims 11-13 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Traumeel® (AN, Product Label for Traumeel®. Homeopathic Ointment, 1995.) and Epicure (AM, Product Label for Unscented Epicure Crystal Sports Cream. Natural Homeopathic Pain Reliever, 1996.). Newly applied as necessitated by amendment.

Applicant's claimed invention was set forth above.

Traumeel® teaches a formulation for topical use comprising herbal active

ingredients and a base suitable for topical penetration of the skin, wherein the herbal active ingredients comprise: homeopathic preparations of Bellis perennis, Calendula officinalis, Hamamelis virginiana, Arnica Montana, Hypericum perforatum and Aconitum napellus, within the claim-designated amounts of each ingredient, as instantly claimed by Applicant.

In another instance, Epicure teaches a formulation, Epicure Crystal, for topical use comprising herbal active ingredients and a gel base suitable for topical penetration of the skin, wherein the herbal active ingredients comprise: homeopathic preparations of Bellis perennis, Arnica Montana, Hypericum perforatum, Aconitum napellus, Ledum palustre, and Ruta graveolens, within the claim-designated amounts of each ingredient, as instantly claimed by Applicant. The referenced composition is a pain-relief gel.

Each of the references anticipates the claimed subject matter.

Claim 1, as amended, and Claims 10-13 is/remains rejected under 35 U.S.C. 102(b) as being anticipated by http://www.homeopathyhome.com/services/rshop/vshoppe/topicals.shtml (X, Natural Health Products), as evidenced by the teachings of Internet Archive Wayback Machine (U1). Newly applied as necessitated by amendment.

Applicant's claimed invention was set forth above.

Natural Health Products teaches a formulation for topical use comprising Aconitum napellus 1X, Arnica montana 1X, Belladonna 1X, Hammamelis virginia 1X,

Hypericum performatum 1X, Ruta graveolens 1X and Symphytum officinale 1X in th form of a cream, which is used for the relief of pain and inflammation.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

Claim 1, as amended, and Claims 10-14, 19 and 20 is/remain rejected under 35 U.S.C. 103(a) as being unpatentable over King Bio Natural Medicines (U) in view of Diec et al. (A*). The rejection stands for the reasons set forth in the previous office action and set forth below.

Applicant's arguments have been fully considered but they are not deemed persuasive because the cited references provide the suggestions and motivation to the claimed invention.

Applicant's claimed invention of Claims 1 and 10-13 was set forth above. Applicant further claims the formulation of claim 1 or claim 10 or claim 12, further comprising a gel base comprising water, glycerine, a polyacrylic acid resin thickener, triethanolamine and methylparaben.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re*

Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the primary reference of King Bio Natural Medicines was relied upon for the reasons set forth in the previous Office action and for the reasons set forth above. Because the teachings of King Bio Natural Medicines taught the instantly claimed invention except for a gel base comprising water, glycerine, a polyacrylic acid resin thickener, triethanolamine and methylparaben, the secondary reference of Diec was relied upon because Diec taught a gel comprising water, glycerine, a polyacrylic acid resin thickener, triethanolamine and methylparaben that was useful in the making of cosmetic or dermatological preparations. Applicant's main argument is directed to the idea that the rejection made against the claims under 35 U.S.C. 103(a) is improper because "the '911 Stress Control 2 oz Liquid' is an oral drug for internal stress" whereas "the claimed formulation is for topical analgesic pain relief"; and, therefore, "It would not have been obvious to those of ordinary skill in the art of homeopathy to use an oral drug for topical pain relief." Applicant further argues that the teachings of Diec fail to overcome the limitations of the referenced composition because Diec does not teach or reasonably suggest that an oral drug for internal stress can be modified as a topical analgesic pain relief formulation. Again, each and every argument of Applicant has been fully considered. However, Applicant's arguments are neither persuasive nor commensurate in scope to the limitations of the claimed invention, since the claims as drafted do not direct the instantly claimed invention to a topical analgesic pain relief formulation. Moreover, it is unclear as to why Applicant has defined the composition taught by King Bio Natural Medicines as an oral drug. Nonetheless, if the referenced composition is indeed an oral

drug and even if Diec fails to expressly provide a motivation to modify an oral drug for topical use, Diec does teach that the ingredients of his invention can be used in the making of gel-based compositions in the form of aerosols, which can be sprayed from aerosol containers, such as the aerosol container containing the composition taught by King Bio Natural Medicines, in Column 27, lines 5-11. Thus, adding the gel-based ingredients taught by Diec to the composition taught by composition taught by King Bio Natural Medicines to provide the instantly claimed invention would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made because it was well known in the art of pharmacy that the delivery of herbal active ingredients via oral administration in the form of a liquid spray could be optimized by modifying the liquid oral drug to a gel form by adding a base comprising the claim-designated ingredients, wherein the base was suitable for topical penetration of the skin.

Thus, with King Bio Natural Medicines teaching formulation, "911 Stress Control 2 oz Liquid", comprising homeopathic preparation of *Bryonia alba* and homeopathic preparations of *Bellis perennis, Calendula officinalis, Arnica Montana, Hypericum perforatum* and *Aconitum napellus*, wherein each ingredient is in equal volumes of 10X, 30X, and 100X potencies in a pure water base; and with Diec providing a gel-based composition comprising the instantly claimed ingredients for use in making of pharmaceutical compositions for the delivery of liquid solutions containing active agents to the skin, it would have been obvious to one of ordinary skill in the art to modify the composition taught by King Bio Natural Medicines by adding the claim-designated gel

base ingredients because Diec suggested that aerosol in the form of gels have broad diversity of uses, including skin formulations, cosmetic and dermatological preparations.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claim 1, as amended, and Claims 11-14 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Epicure () in Diec et al. (A*). Newly applied as necessitated by amendment.

Applicant's claimed invention of Claims 1 and 10-13 was set forth above. Applicant further claims the formulation of claim 1 or claim 12, further comprising a gel base comprising water, glycerine, a polyacrylic acid resin thickener, triethanolamine and methylparaben.

The teachings of Epicure are set forth above. Epicure teaches the instantly claimed invention except for wherein the gel base comprises water, glycerine, a polyacrylic acid resin thickener, triethanolamine and methylparaben. However, it would have been obvious to one of ordinary skill in the art to modify the formulation taught by Epicure by replacing the gel base contained therein the composition taught by Epicure with a gel comprising the instantly claimed ingredients because at the time the invention was made Diec taught a gel comprising water, glycerine, a polyacrylic acid resin thickener, triethanolamine and methylparaben that was useful in the making of cosmetic or dermatological preparations. At the time the invention was made, one of ordinary

skill in the art would have been motivated and one would have had a reasonable expectation of success to modify the Epicure composition by replacing the gel base contained therein with the ingredients comprising the gel base taught by Diec because Diec taught that the referenced gels had broad diversity of uses, including skin formulations, cosmetic and dermatological preparations, and medical/pharmaceutical formulations (*See* Column 4, lines 34-40.) and delivered in the form of an aerosol spray (*See* Column 27, lines 5-10). Moreover, the replacement of one base gel for another base gel for use in the making of a formulation for topical application and penetration of the skin, wherein the formulation comprised therapeutic active agents, would have been no more than a matter of judicious selection to one of skill in the art to provide a result effect variable for the delivery and penetration of therapeutic agents of the skin, given that gel formulations were known in the art as an acceptable vehicle of topical formulations comprising bioactive agents.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele C. Flood

MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
December 10, 2005